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Ph. Eur. monographs and biosimilars

24/02/2017 1 Ph Eur monographs and biosimilars Emmanuelle Charton, Ph D European Pharmacopoeia Department European Directorate for the Quality of Medicines & HealthCare

U.S. Pharmacopeia

The monographs of the Ph Eur include quality specifications for many unfinished products or "drug substances" as well as for some finished products Monographs in the European Pharmacopoeia exist for many approved biosimilars...

Mandatory Public Drug Quality Standards Increase Access to ...

The monographs of the Ph Eur include quality specifications for many unfinished products or "drug substances" as well as for some finished products Monographs in the European Pharmacopoeia exist for many approved biosimilars—eg, human growth hormone (somatropin), erythropoietin (epoetin), filgrastim, and insulin¹⁰ In addition, the Ph

Modern European Pharmacopoeia Future Trends

Biosimilars: Ph Eur expectations Biosimilarity relies on a combination of : quality, safety and efficacy PhEur monographs play an important role during the development of similar biological products as they should be used for method qualification and validation, even if compliance to the Ph Eur...

An MHRA perspective on bioassays

Content • General expectations for bioassays • Potency and effector functions for biosimilars • New Ph Eur monographs for etanercept and infliximab • A regulator's perspective on some novel methods and

Elaborating European Pharmacopoeia monographs for ...

Elaborating Ph Eur monographs for biotherapeutic proteins using substances from a single source 129 Elaborating European Pharmacopoeia with the development of biosimilars 43 Monograph vs ...

EDQM Viewpoint on the Role of the Ph. Eur. in the Field of ...

Ph Eur provides specifications, harmonised approach for similar products/product classes single common quality standard for medicines throughout Europe Ph Eur sets quality standards for biologicals, whether or not such products were to be submitted/approved as biosimilars Ph Eur monographs ...

Complexity in the making: non-biological complex drugs ...

Ph Eur monographs when requesting marketing authorization, superseding all previous directives With the task of protecting public health by applying one common compulsory standard in its Member States, the Ph Eur...

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affected Ph Eur monographs had been proposed, any changes required to BP monograph for Menotropin would be considered The Secretariat reported that the guideline had been published and that the three Ph Eur revisions were available for comment as part of Pharmeuropa 283 The monographs ...

BRITISH PHARMACOPOEIA COMMISSION

hydrates, the descriptor 'anhydrous' will be deleted from the title of 25 Ph Eur monographs and that the change would be implemented by means of the Ph Eur 9th Edition Members will be informed of any ...

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